

CLAIMS

What is claimed is:

1. A method for inducing cell death in cancer cells, the method comprising treating cancer cells with an effective amount of TRAIL sufficient to induce apoptosis in at least a portion of the treated cancer cells.
2. A method for inducing cell death in cancer cells, the method comprising treating cancer cells with an effective amount of TRAIL and an effective amount of an antiprogesterin sufficient to induce apoptosis in at least a portion of the treated cancer cells.
3. The method of claim 2, wherein the antiprogesterin comprises Mifepristone.
4. A method for treating cancer by inducing cell death in cancer cells, the method comprising treating cancer cells with a pharmaceutical composition comprising an effective amount of TRAIL and an effective amount of Mifepristone sufficient to induce apoptosis in at least a portion of the treated cancer cells.
5. The method of claim 4, wherein the cancer cells are treated with Mifepristone prior to being treated with TRAIL.
6. The method of claim 4, wherein the cancer cells are treated with Mifepristone and TRAIL concurrently.
7. The method of claim 4, wherein the dose of TRAIL in said pharmaceutical composition results in a local concentration of TRAIL at the tumor which ranges from 1 to 1,000 ng/ml.

8. The method of claim 4, wherein the dose of TRAIL in said pharmaceutical composition results in a local concentration of TRAIL at the tumor which ranges from 200 to 600 ng/ml.

9. The method of claim 4, wherein the dose of TRAIL in said pharmaceutical composition results in a local concentration of TRAIL at the tumor which ranges from 350 to 450 ng/ml.

10. The method of claim 4, wherein the dose of Mifepristone in said pharmaceutical composition results in a local concentration of Mifepristone at the tumor which ranges from 1 to 1,000  $\mu$ M.

11. The method of claim 4, wherein the dose of Mifepristone in said pharmaceutical composition results in a local concentration of Mifepristone at the tumor which ranges from 1 to 100  $\mu$ M.

12. The method of claim 4, wherein the dose of Mifepristone in said pharmaceutical composition results in a local concentration of Mifepristone at the tumor which ranges from 5 to 20  $\mu$ M.

13. The method of claim 4, wherein said cancer cells comprise prostate cancer cells.

14. The method of claim 13, wherein said prostate cancer cells comprise androgen responsive cells.

15. The method of claim 13, wherein said prostate cancer cells comprise cells which do not respond to androgen.

16. The method of claim 4, wherein the treatment of cancer cells with TRAIL and Mifepristone is associated with an increase in at least one death receptor in at least a portion of the treated cells.

17. The method of claim 16, further comprising an increase in the death receptor DR4 and/or DR5.

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18. The method of claim 4, wherein the treatment of cancer cells with TRAIL and Mifepristone is associated with an increase in activated caspase enzymes.

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19. The method of claim 18, wherein said activated caspases comprise caspase-8, caspase-7, caspase-9, or caspase-3.

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20. The method of claim 4, wherein the treatment of cancer cells with TRAIL and Mifepristone is associated with an increase in truncated BID protein (tBid) in at least a portion of the treated cells.

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21. The method of claim 4, wherein the treatment of cancer cells with TRAIL and Mifepristone is associated with a reduction in mitochondrial function.

22. The method of claim 4, wherein the treatment of cancer cells with TRAIL and Mifepristone results in an increase in apoptosome formation in at least a portion of the treated cells.

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23. The method of claim 4, further comprising treating said cancer cells with a compound which reduces the concentration of active NFκB in said cells.

24. The method of claim 23, further comprising treating said cancer cells with IκB or an analogue thereof, wherein said analogue comprises a polypeptide which prevents activation of NFκB.

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25. The method of claim 4, wherein the manner of treatment comprises intravenous injection of said pharmaceutical composition.

26. The method of claim 4, in combination with other means of treatment such as surgery, chemotherapy, or radiation therapy.

27. A composition for treating cancer by inducing cell death in cancer cells comprising an effective amount of TRAIL in a pharmaceutical carrier, wherein an effective amount comprises sufficient TRAIL to induce apoptosis in at least a portion of said cancer cells exposed to said composition.

28. A composition for treating cancer by inducing cell death in cancer cells comprising an effective amount of TRAIL and an antiprogesterin in a pharmaceutical carrier, wherein an effective amount comprises sufficient TRAIL and antiprogesterin to induce apoptosis in at least a portion of said cancer cells exposed to said composition.

29. The composition of claim 28, wherein the antiprogesterin comprises Mifepristone.

30. A composition for treating cancer by inducing cell death in cancer cells comprising an effective amount of TRAIL and Mifepristone in a pharmaceutical carrier, wherein an effective amount comprises sufficient TRAIL and Mifepristone to induce apoptosis in at least a portion of said cancer cells exposed to said composition.

31. The composition of claim 30, wherein said Mifepristone and said TRAIL are packaged in such a manner that said Mifepristone is at least partially released for application to the cancer prior to the release of said TRAIL.

32. The composition of claim 30, wherein said Mifepristone and said TRAIL are packaged in such a manner so as to be released substantially simultaneously.

33. The composition of claim 30, wherein the dose of TRAIL results in a local concentration of TRAIL at the tumor which ranges from 1 to 1,000 ng/ml.

34. The composition of claim 30, wherein the dose of TRAIL results in a local concentration of TRAIL at the tumor which ranges from 200 to 600 ng/ml.

35. The composition of claim 30, wherein the dose of TRAIL results in a local concentration of TRAIL at the tumor which ranges from 350 to 450 ng/ml.

36. The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the tumor which ranges from 1 to 1,000  $\mu$ M.

37. The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the tumor which ranges from 1 to 100  $\mu$ M.

38. The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the tumor which ranges from 5 to 20  $\mu$ M.

39. The composition of claim 30, wherein said cancer cells comprise prostate cancer cells.

40. The composition of claim 39, wherein said prostate cancer cells comprise androgen responsive cells.

41. The composition of claim 39, wherein said prostate cancer cells comprise cells which do not respond to androgen.

42. A kit for pharmaceutical treatment of cancer comprising:

(a) a pharmacologically effective amount of TRAIL packaged in a sterile container;

(b) a pharmacologically effective amount of an antiprogestin packaged in a sterile container;

(c) at least one aliquot of a pharmaceutical carrier; and

(d) instructions for application of said TRAIL and said antiprogesterone to a patient having cancer.

43. The kit of claim 42, wherein said antiprogesterone comprises Mifepristone.

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44. The kit of claim 42, wherein said cancer comprises prostate cancer.

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